

(c) The Director and Deputy Directors, CDRH, the Director and Deputy Director, OSB, CDRH, and the Director and Deputy Director, DSS, OSB, CDRH, are authorized to grant or revoke exemptions and variances from reporting requirements under § 803.19 of this chapter.

[64 FR 4965, Feb. 2, 1999]

§ 5.99 Issuance of notices relating to proposals and orders for debarment and denial of an application to terminate debarment.

The Director and Deputy Director, Center for Drug Evaluation and Research (CDER), the Director and Deputy Director, Center for Veterinary Medicine (CVM), and the Director and Associate Director for Policy Coordination and Public Relations, Center for Biologics Evaluation and Research (CBER) are authorized to issue the following notices under section 306 of the Federal Food, Drug, and Cosmetic Act (the act) which relate to the assigned functions of their organizations:

(a) Notices of opportunity for hearing on proposals for mandatory or permissive debarment.

(b) Notices ordering debarment when opportunity for a hearing has been waived.

(c) Notices ordering debarment where the person notifies the agency that the person acquiesces to debarment under section 306(c)(2)(B) of the act.

(d) Notices of opportunity for hearing on proposals denying an application to terminate debarment under section 306(d)(3) of the act.

(e) Orders denying an application to terminate debarment under section 306(d)(3) of the act when opportunity for a hearing has been waived.

[61 FR 8215, Mar. 4, 1996; 61 FR 11545, Mar. 21, 1996; 61 FR 14375, Apr. 1, 1996]

Subpart C—Organization

§ 5.100 Officials authorized to make certification under 5 U.S.C. 605(b) for any proposed and final rules.

The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to decisions made under the Regulatory Flexibility Act (5 U.S.C. 605(b)), to certify that a proposed or

final rule, if issued, will not have a significant economic impact on a substantial number of small entities:

(a) The Associate Commissioner for Regulatory Affairs (ACRA).

(b) The Director, Center for Biologics Evaluation and Research (CBER).

(c) The Director, Center for Drug Evaluation and Research (CDER).

(d) The Director, Center for Devices and Radiological Health (CDRH).

(e) The Director, Center for Food Safety and Applied Nutrition (CFSAN).

(f) The Director, Center for Veterinary Medicine (CVM).

(g) Other FDA Officials authorized to issue FEDERAL REGISTER documents.

[62 FR 48757, Sept. 17, 1997]

§ 5.200 Headquarters.

The central organization of the Food and Drug Administration consists of the following:

OFFICE OF THE COMMISSIONER.¹

Office of the Chief Counsel.
Office of Executive Secretariat.
Office of Equal Employment and Civil Rights.
Office of the Administrative Law Judge.
Office of Internal Affairs.

OFFICE OF OPERATIONS.

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH.²

Office of the Center Director

Scientific Advisors and Consultants Staff.
Equal Employment Opportunity Staff.
Quality Assurance Staff.
Congressional and Public Affairs Staff.
Regulations and Policy Staff.

Office of Management

Division of Planning, Evaluation, and Budget.
Division of Management Services.
Division of Information Technology Operations.
Division of Infrastructure and Systems Development.

Office of Compliance and Biologics Quality

Team Biologics Liaison Staff.
Division of Case Management.
Division of Inspections and Surveillance.

¹Mailing address: 5600 Fishers Lane, Rockville, MD 20857.

²Mailing address: 1401 Rockville Pike, Rockville, MD 20852-1448.

§ 5.200

Division of Manufacturing and Product Quality.

Office of Blood Research and Review

Division of Transfusion Transmitted Diseases.

Division of Hematology.

Division of Blood Applications.

Division of Blood Establishment and Products.

Office of Therapeutics Research and Review

Division of Cytokine Biology.

Division of Cellular and Gene Therapies.

Division of Hematologic Products.

Division of Monoclonal Antibodies.

Division of Clinical Trial Design and Analysis.

Division of Application Review and Policy.

Regulatory Information Management Staff.

Office of Vaccines Research and Review

Division of Allergenic Products and Parasitology.

Division of Bacterial Products.

Division of Viral Products.

Division of Vaccines and Related Products Applications.

Office of Communication, Training, and Manufacturers Assistance

Division of Congressional and Public Affairs.
Division of Manufacturers Assistance and Training.

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION.³

Office of the Center Director

Equal Employment Opportunity Staff.

Office of Policy, Planning, and Strategic Initiatives

Executive Operations Staff.

Office of Programs

Beltsville Technical Operations Staff.

Office of Cosmetics and Colors

Division of Programs and Enforcement Policy.

Division of Science and Applied Technology.

Office of Food Labeling

Division of Programs and Enforcement Policy.

Division of Technical Evaluation.

Division of Science and Applied Technology.

Office of Premarket Approval

Division of Product Policy.

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Division of Petition Control.

Division of Health Effects Evaluation.

Division of Molecular Biological Research and Evaluation.

Division of Product Manufacture and Use.

Office of Plant and Dairy Foods and Beverages

Division of Programs and Enforcement Policy.

Division of Virulence Assessment.

Division of Pesticides and Industrial Chemicals.

Division of Natural Products.

Division of Food Processing and Packaging.

Office of Seafood

Division of Special Programs.

Division of Programs and Enforcement Policy.

Division of Science and Applied Technology.

Office of Special Nutritionals

Clinical Research and Review Staff.

Division of Programs and Enforcement Policy.

Division of Science and Applied Technology.

Office of Special Research Skills

Division of Toxicology Research.

Division of Microbiological Studies.

Office of Systems and Support

Quality Assurance Staff.

Office of Constituent Operations

Consumer Education Staff.

Legislative Activities Staff.

Industry Activities Staff.

International Activities Staff.

Office of Field Programs

Division of Enforcement and Programs.

Division of HACCP Programs.

Division of Cooperative Programs.

Office of Management Systems

Safety Management Staff.

Division of Information Resources Management.

Division of Planning and Resources Management.

Office of Scientific Analysis and Support

Division of Mathematics.

Division of General Scientific Support.

Division of Market Studies.

CENTER FOR DRUG EVALUATION AND RESEARCH.⁴

Office of the Center Director

Advisors and Consultants Staff.

³Mailing address: 200 C St. SW., Washington, DC 20204.

⁴Mailing address: 1451 Rockville Pike, Rockville MD 20857

Food and Drug Administration, HHS

§ 5.200

Equal Employment Opportunity Staff.
Pilot Drug Evaluation Staff.
Executive Operations Staff.
Regulatory Policy Staff.

Office of Management

Special Projects Staff.
Division of Planning, Evaluation, and Resource Management.
Division of Management Services.

Office of Training and Communications¹

Freedom of Information Staff.
Division of Communications Management.
Division of the Medical Library.
Division of Training and Development.

Office of Compliance⁵

Division of Manufacturing and Product Quality.
Division of Scientific Investigations.
Division of Prescription Drug Compliance and Surveillance.
Division of Labeling and Nonprescription Drug Compliance.

Office of Information Technology¹

Quality Assurance Staff.
Technology Support Services Staff.
Division of Data Management and Services.
Division of Applications Development and Services.
Division of Infrastructure Management and Services.

Office of Review Management⁴

Advisors and Consultants Staff.

Office of Drug Evaluation I

Division of Cardio-Renal Drug Products.
Division of Drug Marketing, Advertising and Communication.¹
Division of Neuropharmacological Drug Products.
Division of Oncology Drug Products.

Office of Drug Evaluation II

Division of Metabolic and Endocrine Drug Products.
Division of Pulmonary Drug Products.
Division of Reproductive and Urologic Drug Products.

Office of Drug Evaluation III

Division of Anesthetic, Critical Care, and Addiction Drug Products
Division of Gastro-Intestinal and Coagulation Drug Products.
Division of Medical Imaging and Radiopharmaceutical Drug Products.

⁵ Mailing address: 7520 Standish Pl., Rockville, MD 20857

Office of Drug Evaluation IV⁶

Division of Anti-Infective Drug Products.
Division of Anti-Viral Drug Products.
Division of Special Pathogen and Immunologic Drug Products.

Office of Drug Evaluation V

Division of Anti-Inflammatory, Analgesic, and Ophthalmologic Drug Products.
Division of Dermatologic and Dental Drug Products.
Division of Over-The-Counter Drug Evaluation.

Office of Epidemiology and Biostatistics¹

Quantitative Methods and Research Staff.
Division of Biometrics I.⁴
Division of Pharmacovigilance and Epidemiology.¹
Division of Biometrics II.
Division of Biometrics III.
Division of Biometrics IV.⁶

Office of Pharmaceutical Science⁴

Quality Implementation Staff.¹
Operations Staff.⁴

Office of Clinical Pharmacology and Biopharmaceutics

Pharmacometrics Staff.
Division of Pharmaceutical Evaluation I.⁴
Division of Pharmaceutical Evaluation II.¹
Division of Pharmaceutical Evaluation III.⁶

Office of Generic Drugs⁷

Division of Bioequivalence.
Division of Chemistry I.
Division of Chemistry II.
Division of Labeling and Program Support.

Office of New Drug Chemistry¹

Division of New Drug Chemistry I.⁴
Division of New Drug Chemistry II.¹
Division of New Drug Chemistry III.⁸

Office of Testing and Research¹

Regulatory Research and Analysis Staff.
Laboratory of Clinical Pharmacology.⁹
Division of Applied Pharmacology Research.¹⁰

⁶ Mailing address: 9200 Corporate Blvd., Rockville, MD 20850

⁷ Mailing address: 7500 Standish Pl., Rockville, MD 20855

⁸ Mailing address: 9201 Corporate Blvd., Rockville, MD 20850

⁹ Mailing address: Four Research Ct., Rockville, MD 20850

¹⁰ Mailing address: 8301 Muirkirk Rd., Rockville, MD 20708

§ 5.200

Division of Testing and Applied Analytical Development.¹¹

Division of Product Quality Research.¹

Office of Regulatory Affairs¹²

Contaminants Policy Coordination Staff.
Equal Employment Opportunity Staff.
Strategic Initiatives Staff.

Office of Resource Management

Division of Planning, Evaluation, and Management.
Division of Information Systems.
Division of Human Resource Development.
Division of Management Operations.

Office of Enforcement

Medical Products Quality Assurance Staff.
Division of Compliance Management and Operations.
Division of Compliance Policy.

Office of Regional Operations

Division of Federal-State Relations.
Division of Field Science.
Division of Emergency and Investigational Operations.
Division of Import Operations and Policy.

Office of Criminal Investigations¹³

Northeast Regional Office.¹⁴
Pacific Area Office.¹⁵
Southeast Regional Office.¹⁶
Southwest Regional Office.¹⁷
Central Regional Office.¹⁸

NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH.¹⁹

Office of the Center Director

Environmental Health and Program Assurance Staff.
Equal Employment Opportunity Staff.
Scientific Coordination Staff.
Technology Advancement Staff.

¹¹Mailing address: 1114 Market St., St. Louis, MO 63101

¹²Mailing address: 5600 Fishers Lane, Rockville, MD 20857

¹³Mailing address: 7500 Standish Pl., rm. 250N, Rockville, MD 20855.

¹⁴Mailing address: 850 Third Ave., Brooklyn, NY 11232.

¹⁵Mailing address: 13301 Clay St., Oakland, CA 94512.

¹⁶Mailing address: 60 Eighth St. NE., Atlanta, GA 30309.

¹⁷Mailing address: 7920 Elmbrook Rd., Dallas, TX 75247.

¹⁸Mailing address: 900 U.S. Customhouse, Second Chestnut St., Philadelphia, PA 19106.

¹⁹Mailing address: Jefferson, AR 72079-9502.

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Office of Planning and Resource Management

Planning Staff.
Evaluation Staff.
Financial Management Staff.

Office of Research

Research Coordination Staff.
Biomarkers Laboratory Staff.
Division of Reproductive and Developmental Toxicology.
Division of Genetic Toxicology.
Division of Biochemical Toxicology.
Division of Nutritional Toxicology.
Division of Biometry and Risk Assessment.
Division of Chemistry.
Division of Microbiology.
Division of Neurotoxicology.

Office of Research Support

Veterinary Services Staff.
Information Technology Staff.
Division of Facilities Engineering and Maintenance.
Division of Administrative Services.

CENTER FOR VETERINARY MEDICINE.²⁰

Office of the Center Director

Office of Management and Communications

Administrative Staff.
Communications Staff.
Program Planning and Evaluation Staff.
Information Resources Management Staff.

Office of New Animal Drug Evaluation

Division of Therapeutic Drugs for Food Animals.
Division of Biometrics and Production Drugs.
Division of Therapeutic Drugs for Non-Food Animals.
Division of Human Food Safety.
Division of Manufacturing Technologies.

Office of Surveillance and Compliance

Division of Epidemiology and Surveillance.
Division of Animal Feeds.
Division of Compliance.

Office of Research

Administrative Staff.
Division of Residue Chemistry.
Division of Animal Research.

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH.²¹

Office of the Center Director

Equal Employment Opportunity Staff.

²⁰Mailing address: 7500 Standish Pl., MPN-2, Rockville MD 20855

²¹Mailing address: 9200 Corporate Blvd., Rockville, MD 20850

Food and Drug Administration, HHS

§ 5.200

Office of Systems and Management

Integrity, Committee and Conference Management Staff.
Division of Management Operations.
Financial Resources Staff.
Division of Information Dissemination.
Division of Information Technology Management.
Division of Planning, Analysis and Finance.

*Office of Compliance*¹

Promotion and Advertising Policy Staff.
Division of Program Operations.
Division of Bioresearch Monitoring.
Division of Enforcement I.
Division of Enforcement II.
Division of Enforcement III.

Office of Device Evaluation

Program Operations Staff.
Program Management Staff.
Division of Cardiovascular, Respiratory, and Neurological Devices.
Division of Reproductive, Abdominal, Ear, Nose, and Throat, and Radiological Devices.
Division of General and Restorative Devices.
Division of Clinical Laboratory Devices.
Division of Ophthalmic Devices.
Division of Dental, Infection Control, and General Hospital Devices.

Office of Science and Technology

Division of Mechanics and Materials Science.
Division of Life Sciences.
Division of Physical Sciences.
Division of Electronics and Computer Sciences.
Division of Management, Information, and Support Services.

Office of Health and Industry Programs

Program Operations Staff.
Division of Device User Program and Systems Analysis.
Division of Small Manufacturers Assistance.
Division of Mammography Quality and Radiation Programs.
Division of Communication Media.

Office of Surveillance and Biometrics

Division of Biostatistics.
Division of Postmarket Surveillance.
Division of Surveillance Systems.

*Office of Orphan Products Development.*¹

OFFICE OF SCIENCE.

OFFICE OF EXTERNAL AFFAIRS.¹

Industry and Small Business Liaison Staff.
Medwatch Staff.

Office of Public Affairs

Press Relations Staff.

Communications Staff.
Freedom of Information Staff.
Speechwriting Staff.
Management Staff.
Broadcast Media Staff.

Office of Health Affairs

Medicine Staff.
Health Assessment Policy Staff.

Office of Legislative Affairs

Congressional Affairs Staff I.
Congressional Affairs Staff II.
Special Projects Staff.

Office of Consumer Affairs

Office of AIDS and Special Health Issues

Office of Women's Health

Office of International Affairs

OFFICE OF MANAGEMENT AND SYSTEMS

Operations Coordination Staff.
Executive Management Staff.

Office of Planning and Evaluation

Planning and Management Communications Staff.
Evaluation and Analysis Staff.
Economics Staff.

Office of Information Resources Management

Planning Resources and Information Systems Management Staff.
Administrative Management Staff.
Division of Information Services and Policy.
Division of Operations and Technology Services.
Division of Software Engineering Services.
Division of Facilities.
Telecommunications and Planning Support.

Office of Financial Management

Division of Financial Systems.
Division of Accounting.
Division of Budget Formulation.

Office of Human Resources and Management Services

Division of Personnel Operations I.
Division of Personnel Operations II.
Division of Employee and Labor Management Relations.
Division of Recruitment and Staffing.
Division of Compensation Benefits and Training.
Division of Management Systems and Policy.
Division of Personnel Operations III.

§ 5.205

*Office of Facilities, Acquisitions and Central Services*²²

Policy Evaluation and Support Staff.
Division of Contracts and Procurement Management.
Division of Construction and Facilities Support Contracting.
Division of Central Services.
Division of Real Property Management.
Project Analysis and Evaluation Staff.
Division of Facilities Planning, Engineering and Safety.
Facilities Planning Staff.
FDA Safety Staff.

OFFICE OF POLICY

Regulations Policy and Management Staff.
Policy Development and Coordination Staff.
Policy Research Staff.
International Policy Staff.

[63 FR 18314, Apr. 15, 1998]

§ 5.205 Chief Counsel, Food and Drug Administration.

The Chief Counsel to the Commissioner of Food and Drugs is the Associate General Counsel, Food and Drug Division, Office of the General Counsel, Department of Health and Human Services, Room 6-57, 5600 Fishers Lane, Rockville, MD 20857.

[46 FR 8455, Jan. 27, 1981, as amended at 56 FR 8709, Mar. 1, 1991. Redesignated at 62 FR 13824, Mar. 24, 1997]

§ 5.210 FDA Public Information Offices.

(a) *Dockets Management Branch (HFA-305)*. The Dockets Management Branch Public Room is located in rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. Telephone: 301-443-1753.

(b) *Freedom of Information Staff (HFI-35)*. The Freedom of Information Public Room is located in rm. 12A-30, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD 20857. Telephone: 301-827-6500

(c) *Press Relations Staff (HFI-40)*. The Press Offices are located in rm. 15A-07, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD 20857. Telephone: 301-827-6242; and in rm. 3807, FB-8, 200 C St. SW., Washington, DC 20204. Telephone 202-245-1141.

[63 FR 18317, Apr. 15, 1998]

²² Mailing address: 12420 Parklawn Dr., Rockville, MD 20857

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§ 5.215 Field structure.

NORTHEAST REGION

Regional Field Office: 850 Third Ave., Brooklyn, NY 11232.

Northeast Regional Laboratory: 850 Third Ave., Brooklyn, NY 11232-1593.

New York District Office: 850 Third Ave., Brooklyn, NY 11232-1593.

New England District Office: One Montvale Ave., Stoneham, MA 02180.

Buffalo District Office: Olympic Towers, 300 Pearl St., Buffalo, NY 14202.

CENTRAL REGION

Regional Field Office: U.S. Customhouse, Second and Chestnut Sts., rm. 900, Philadelphia, PA 19106.

Baltimore District Office: 900 Madison Ave., Baltimore, MD 21201-2199.

Cincinnati District Office: 1141 Central Pkwy., Cincinnati, OH 45202-1097.

New Jersey District Office: Waterview Corporate Center, 10 Waterview Blvd., 3d Floor, Parsippany, NJ 07054.

Philadelphia District Office: U.S. Customhouse, Second and Chestnut Sts., rm. 900, Philadelphia, PA 19106.

Chicago District Office: 300 South Riverside Plaza, suite 550, South Chicago, IL 60606.

Detroit District Office: 1560 East Jefferson Ave., Detroit, MI 48207-3179.

Minneapolis District Office: 240 Hennepin Ave., Minneapolis, MN 55401-1912.

SOUTHEAST REGION

Regional Field Office: 60 Eighth St. NE., Atlanta, GA 30309.

Southeast Regional Laboratory: 60 Eighth St. NE., Atlanta, GA 30309.

Atlanta District Office: 60 Eighth St. NE., Atlanta, GA 30309.

Nashville District Office: 297 Plus Park Blvd., Nashville, TN 37217.

New Orleans District Office: 4298 Elysian Fields Ave., New Orleans, LA 70122.

Florida District Office: 555 Winderley Pl., suite 200., Maitland, FL 32751.

San Juan District Office: 466 Fernandez Juncos Ave., San Juan, PR 00901-3223.

SOUTHWEST REGION

Regional Field Office: 7920 Elmbrook Rd., Dallas, TX 75247-4982.

Dallas District Office: 3310 Live Oak St., Dallas, TX 75204.

Denver District Office: Bldg. 20, Denver Federal Center, Sixth and Kipling Sts., P.O. Box 25087, Denver, CO 80225-0087.

Kansas City District Office: 11630 West 80th St., Lenexa, KS 66214.

St. Louis Branch: 12 Sunnen Dr., St. Louis, MO 63143.